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United States District Court, Northern District of Illinois

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Name of Assigned Judge or Magistrate Judge		Joan B. G	ottschall	Sitting Judge if Other than Assigned Judge					
CASE NUMBER		00 C 5092, 01 C		DATE	3/26/:	2003			
CASE TITLE		Abbott Laboratories, et al. vs. Impax Laboratories, Inc.							
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(9)		This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to] ☐ FRCP4(m) ☐ Local Rule 41.1 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).							
(10) E [Other docket entry] ENTER MEMORANDUM OPINION AND ORDER: Defendant's Motion for Partial Summary Judgment of Non-Infringement [71-1 for 00 C 5092; 0-1 for 00 C 7865; 0-1 for 01 C 1648] is granted.									
(11)	= [For f	urther detail see order	attached to the or.	iginal minute order.]		i		
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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTE, LABORATOIRES FOURNIER S.A.))		
Plaintiffs,) 00 C 5092) 00 C 7865) 01 C 1648		DOGGETER
V,)) Judg	ge Joan B. Gottschall	MAR 2 8 2003
IMPAX LABORATORIES, INC. Defendant.)))		

MEMORANDUM OPINION AND ORDER

Plaintiffs Abbott Laboratories ("Abbott"), Fournier Industrie Et Sante, and Laboratoires Fournier S.A. (all three plaintiffs collectively "Fournier") have brought this patent infringement action against Impax Laboratories, Inc. ("Impax") alleging that Impax has infringed Fournier's United States Patent No. 4,895,726 (the '726 patent"). Before the court is defendant Impax's motion for partial summary judgment of non-infringement. For the reasons explained below, Impax's motion is granted.

Background

Plaintiffs are the owners and a licensee of the '726 patent. The '726 patent is directed to "a novel dosage form of fenofibrate containing fenofibrate and a solid surfactant which have been comicronized" and "to the method for the preparation of this dosage form and its use for improving

[&]quot;Surfactant" is an agent that interacts with the surfaces of poorly soluble substances, such as fenofibrate, to help them dissolve. (Fournier Resp. at 3-4.)

the bioavailability in vivo." According to the patent, the invention proposed a novel therapeutic composition, containing fenofibrate and a solid surfactant that have been co-micronized, which is used in the oral treatment of hyperlipidemia and hypercholesterolemia. ('726 patent, col. 1, 1l. 4-10.) The medication is marketed by Abbott under the name TRICOR® in 67 mg, 134 mg, and 200 mg dosage strengths. According to Fournier, the novelty of the invention derives from the fact that a co-micronized mixture of fenofibrate and a solid surfactant have better dissolution characteristics, and therefore better bioavailability, than separately micronized (or non-micronized) fenofibrate and surfactant which are mixed, but not micronized, together.

Defendant Impax is a manufacturer of generic drug products. Pursuant to the Hatch-Waxman Act, Impax filed an Abbreviated New Drug Application ("ANDA"), 21 U.S.C. § 355(j), seeking the Food and Drug Administration's approval to market a generic micronized fenofibrate product in three dosage forms: 67mg, 134 mg, and 200mg. Impax's ANDA discloses that: (1) Impax uses premicronized fenofibrate in its products; and (2) at no time does Impax co-micronize fenofibrate and a solid surfactant in the absence of other excipients. (Impax 56.1(a)(3) St. at ¶ 52-59.) As part of the ANDA, Impax submitted a "Paragraph (IV)" certification referring to the '726 patent, stating "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV). After receiving the required notices from Impax, Fournier filed three complaints – one for each of Impax's three proposed dosage forms – each asserting that Impax's fenofibrate product infringed the '726 patent.

² Paragraph (IV) certification required Impax to give notice of the certification to the patentee. 21 U.S.C. § 355(j)(2)(B)(I). A Paragraph (IV) certification is often an invitation to a patent infringement suit. Bayer AG v. Elan Pharmaceutical Research Corp., 212 F.3d 1241, 1244-45 (Fed. Cir. 2000).

The three lawsuits were later consolidated as they all relate to the same issues.

The present dispute centers on the proper interpretation of the terms "co-micronized" and "co-micronization" as used in claims 1 and 10 of the '726 patent. Claim 1 states:

A therapeutic composition, which is presented in the form of gelatin capsules and which is useful especially in the oral treatment of hyperlipidemia and hypercholesterolemia, said composition containing a **co-micronized** mixture of particles of fenofibrate and a solid surfactant, wherein the mean particle size of said **co-micronized** mixture is less than $15 \, \mu m$.

('726 patent, col. 5, ll. 6-12 (emphasis added).) Claim 10 states:

A method for improving the bioavailability to fenofibrate in vivo, which comprises **co-micronization** of the fenofibrate and a solid surfactant, the said **co-micronization** being carried out by micronization of a fenofibrate/solid surfactant mixture until the particle size of the powder obtained is less than $15 \mu m$.

(Id., col. 6, 11. 20-25 (emphasis added).) Fournier argues that Impax's product, which utilizes premicronized fenofibrate, infringes the '726 patent. Specifically, Fournier argues that Impax's product contains a mixture of fenofibrate and a solid surfactant that have been co-micronized, or reduced in size together. (Fournier Resp. at 2.) Although acknowledging that Impax's product starts with already micronized (i.e., pre-micronized) fenofibrate, Fournier argues that the fenofibrate in Impax's product is further micronized (i.e., co-micronized) with a surfactant during certain steps of the manufacturing process. (Id. at 5.)

The Novopharm Action

Based on the same claims at issue in this lawsuit, Fournier brought suit against Novopharm, a generic drug manufacturer, for infringement of the '726 patent. On March 20, 2002, Judge John W. Darrah granted Novopharm's motion for summary judgment of non-infringement of the '726 patent. Abbott Labs. v. Novopharm Ltd., Consolidated Nos. 00 C 2141, 00 C 5094 and 01 C 1914,

2002 U.S. Dist. LEXIS 4659, at *25-26 (N.D. III. Mar. 19, 2002). As in this case, the critical issue in *Novopharm* was the meaning of "co-micronized" and "co-micronization" as used in claims 1 and 10 of the '726 patent. Relying on the ordinary definitions of the prefix "co" and the word "micronize," the *Novopharm* court determined that "the ordinary meaning of the term 'co-micronized' would be 'to reduce to a fine powder [micronize] with or together." *Id.* at *17. The court held that "co-micronization" and "co-micronized" are distinct from "micronizing fenofibrate by itself." *Id.* at *25. The court further concluded that one skilled in the art reading the claims, specification, and prosecution history could conclude that the term "co-micronized" in claims 1 and 10 "mean[s] that fenofibrate and a solid surfactant have been micronized together in the absence of other excipients." *Id.* at *20-21. Finally, because Novopharm's product utilized fenofibrate that has been micronized by itself, and at no time are fenofibrate and a solid surfactant present in the absence of other excipients, the court granted Novopharm's motion for summary judgment of non-infringement. *Id.* at *25-26.

Analysis

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party has the initial responsibility of demonstrating the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Summary judgment is proper when no "reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Because the determination is a question of fact, summary judgment of infringement is proper if a reasonable jury could find that every limitation of the claims

in question would be met by the products that Impax is likely to sell. Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998).

Summary Judgment of Non-Infringement in Patent Cases

An infringement analysis is a two-step process. The first step is determining the meaning and scope of the patent claims allegedly infringed, also known as claim construction. *Mahurkar v. Arrow Int'l, Inc.*, 160 F. Supp. 2d 927, 932 (N.D. Ill. 2001) (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995)). Courts must construe the claims as a matter of law before turning to the second step, the factual application of those claims to the accused products. *Id.* Summary judgment is appropriate where it is shown that the question of infringement can be reasonably decided only in favor of the movant, keeping in mind that the burden of proving infringement rests with the patentee. *Bai*, 160 F.3d at 1353-54.

In order to interpret a disputed term or phrase, the court first looks to the language of the patent itself, including the claims, the specification, and the prosecution history, as the primary source for construing patent claims. *Mahurkar*, 160 F. Supp. 2d at 932. The language of the claim defines the scope and meaning of that claim. *York Products, Inc. v. Central Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1572 (Fed. Cir. 1996). The language of the claims is to be given its ordinary and accustomed meaning. *Johnson Worldwide Assoc., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999). The court may also review extrinsic evidence, such as treatises and expert testimony, so long as that evidence does not vary or contradict the clear meaning of terms in the claims. *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1369 (Fed. Cir. 2003).

Collateral Estoppel

Impax argues that the doctrine of collateral estoppel, also known as issue preclusion, prevents Fournier from arguing that this court should interpret the pertinent claims differently than did the *Novopharm* court. Collateral estoppel "shields a defendant from having to litigate issues that have been fully and fairly tried in a previous action and decided adversely to a party." *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.* 170 F.3d 1373, 1379 (Fed. Cir. 1999). Collateral estoppel is appropriate if: (1) the issues raised in both proceedings are identical; (2) the issues were actually litigated; (3) the determination of the issue was essential to a final judgment in the first action; and (4) the party against whom estoppel is invoked had a full and fair opportunity to litigate the issues in the first action. *Adair v. Sherman*, 230 F.3d 890, 893 (7th Cir. 2000); *Abbott Labs. v. Dey, L.P.*, 110 F. Supp. 2d 667, 669 (N.D. Ill. 2000); *see also Blonder-Tongue Lab., Inc. v. Univer. of Ill. Found.*, 402 U.S. 313 (1971) (recognizing the use of collateral estoppel in a patent infringement case). Collateral estoppel is not exclusive to patent law and therefore the law of the circuit in which the district court sits applies, in this case Seventh Circuit law. *Pharmacia*, 170 F.3d at 1381 n.4.

It is undisputed that all four of the conditions for applying collateral estoppel to the claim constructions are present here. First, the construction of claims 1 and 10 of the '726 patent are the identical issues presented in the *Novopharm* case. Both parties agree that Judge Darrah construed the same claim language terms "co-micronized" and "co-micronization" that are in dispute in this case. Second, the construction of the disputed terms was actually litigated in *Novopharm*. Fournier and Novopharm briefed and argued the claim construction issues before Judge Darrah. Third, Judge Darrah could not have granted Novopharm summary judgment without first construing the claims at issue, and then comparing them to Novopharm's fenofibrate products, and, therefore, the claim

construction issues were "essential" to support the final judgment rendered. *Jackson Jordan, Inc.*v. *Plasser American Corp.*, 747 F.2d 1567, 1577 (Fed. Cir. 1984). Finally, Fournier had a full and fair opportunity to litigate the issues in the *Novopharm* action. As a result, the court concludes that the doctrine of collateral estoppel applies in this case.

Instead of refuting Impax's argument that the four conditions are met, Fournier argues that a district court is not bound by another court's claim construction. This argument ignores authority stating that collateral estoppel may be applied in the claim construction context. *Abbott Labs.*, 110 F. Supp. 2d at 669-71; *Blonder-Tongue Lab*, 402 U.S. at 349-50. Fournier cites to two footnotes in two related cases to support its argument that collateral estoppel should not be applied in this case. In *Nilssen v. Motorola*, Inc., 80 F. Supp. 2d 921, 924 n.4 (N.D. Ill. 2000), the patentee attempted to enforce a claim construction from a prior litigation against defendants who were not parties to the prior case. That case is clearly distinguishable from the present case where Impax, the defendant, has argued for estoppel. The second case relied upon by Fournier, *Nilssen v. Magnetek, Inc.*, 2000 WL 369747, *1 n.3 (N.D. Ill. 2000), is also readily distinguishable as there was no final order issued after the court construed the claims and, therefore, there was no determination of issues "essential to a final judgment."

Fournier also argues that the court should not apply the doctrine of collateral estoppel because an intervening change in the law, pertinent to the issues in this case, has occurred since the *Novopharm* decision. Specifically, Fournier contends that the Supreme Court's decision in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 122 S. Ct. 1831 (2002), changed the law regarding prosecution-history estoppel's limitation on the doctrine of equivalents. The court disagrees that *Festo* represents an intervening change in the law that is applicable here.

The doctrine of equivalents allows a patentee to claim insubstantial alterations in the patented process that were not captured in drafting the original patent claims, but which could be created through trivial changes. Festo, 122 S. Ct. at 1838. However, prosecution-history estoppel can prevent a patentee from relying on the doctrine of equivalents when the patentee relinquishes subject matter during the prosecution of the patent, either by amendment or argument. Pharmacia, 170 F.3d at 1376-77. Where the original application once embraced a purported equivalent, but the patentee narrowed the claims to obtain the patent or protect its validity, the patentee cannot later assert those surrendered equivalents. Festo, 122 S. Ct. at 1839 (describing estoppel by amendment). In a similar way, "[a[rguments made voluntarily during prosecution may give rise to prosecution history estoppel if they evidence a surrender of subject matter." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F.3d 558, 569 (Fed. Cir. 2000), rev'd on other grounds, 122 S. Ct. 1831 (2002) (describing estoppel by argument). Addressing only estoppel by amendment, the recent Festo decision did not address (or change) the law regarding argument-based estoppel. Instead, the Festo court addressed the "absolute bar" precluding application of the doctrine of equivalents as to certain types of amended claims. Festo, 122 S. Ct. at 1840. Because Judge Darrah's decision did not rely upon amendments to claims during prosecution history, Novopharm, 2002 U.S. Dist. LEXIS 4659, at *24-25 (basing estoppel on the "the arguments made during the prosecution of the patent . . . and the arguments made during reexamination"), but rather on arguments made by Fournier during prosecution of the patent, Festo did not change the law controlling this case.3 Accordingly, the court

³ While the court recognizes that the *Novopharm* court mentions an amendment to claim 1, the court concludes that the stated bases for Judge Darrah's application of prosecution-history estoppel were the *arguments* made by the patentee during prosecution history. *Novopharm*, 2002 U.S. Dist. LEXIS 4659, at *23-24.

rejects Fournier's argument that Festo represents an intervening change in the law.

Finally, Fournier, relying on *Blonder-Tongue Labs*, 402 U.S. at 333, argues that the *Novopharm* court's decision cannot serve as a basis for collateral estoppel because the *Novopharm* court misunderstood the pharmaceutical technology and issues in the '726 patent.⁴ Since *Blonder-Tongue*, the Federal Circuit has made clear that, in a collateral estoppel analysis, a district court should not determine whether the prior finding was correct. *Stevenson v. Sears, Robuck Co.*, 713 F.2d 705, 709 (Fed. Cir. 1983). Rather, the court should focus on whether the patentee had a full and fair chance to litigate the issue in the prior lawsuit. *Id.* Here, Fournier had such an opportunity.

The court notes that even if it were not bound to follow Judge Darrah's ruling, it would nonetheless similarly construe the claims. First, the court would look to the ordinary meaning of "co-micronized" to find that it means "to reduce to a fine powder [micronize] with or together." Dorland's Illustrated Medical Dictionary 368, 389 (29th ed. 2000). Next, as Judge Darrah did, the court looks to the claim language, specification, and prosecution history and concludes that a "co-micronized" mixture includes fenofibrate and a solid surfactant that have been micronized together in the absence of any other excipients. Nowhere in the claims, specification, or prosecution history are any other materials identified as being part of this mixture. Further, in the specification and prosecution history, the patentee distinguished its co-micronized mixture from mixtures obtained by adding a surfactant to fenofibrate, or micronizing fenofibrate by itself, and/or mixing separately micronized fenofibrate and a surfactant. Like Judge Darrah, this court concludes that "co-

⁴ The court further rejects the argument that it should disregard the *Novopharm* decision merely because it is on appeal to the Federal Circuit. Pending post-trial motions do not effect the finality of a judgment and, therefore, do not prevent its preclusive effect. *Pharmacia*, 170 F.3d at 1381.

micronized" and "co-micronization" means that fenofibrate and a solid surfactant have been micronized together in the absence of other excipients.

In addition to arguing that this court should adopt Judge Darrah's construction of claims, Impax argues that this court should further "augment" those constructions. (Impax Mem. at 10.) Impax asserts that its proposed additions to the claim construction of the disputed terms are not inconsistent with Judge Darrah's determinations, and are only meant to clarify, not contradict, the prior court's claim construction. Furthermore, Impax relies on its additional claim constructions as separate and distinct grounds upon which this court may grant summary judgment of non-infringement.

In response, Fournier argues that Impax proposes novel claim constructions that are inconsistent with Judge Darrah's construction. Reasoning that collateral estoppel is designed to "relieve parties of the cost and vexation of multiple lawsuits, conserve judicial resources, and, by presenting inconsistent decisions, encourage reliance on adjudication[,]" *Allen v. McCurry*, 449 U.S. 90, 94 (1980), Fournier argues that the public policy considerations behind collateral estoppel would not be met if Impax's additions and clarifications were considered.

The only case cited by Impax for the proposition that this court may both apply collateral estoppel and change Judge Darrah's construction, is *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). Impax cites that case for the proposition that "collateral estoppel does not bar a different defendant from asserting any claim construction he wishes." (Impax Reply at 7 (emphasis in original).) The court has reviewed that case (which concerns a patent relating to the dry cleaning business) and can find nothing in the case to support Impax's position. The *Markman* court does, in the penultimate paragraph, state that "issue preclusion could not be asserted against new and

independent infringement defendants...[,]" but that clearly refers to an attempt by a plaintiff to have a favorable construction applied to a different defendant in a new case. *Id.* at 391. That simply is not the issue here.

In light of the lack of authority for the proposition that this court may apply collateral estoppel and make adjustments to the prior construction, the court will not alter Judge Darrah's construction in any way. The purpose of collateral estoppel—relieving parties of the cost of multiple lawsuits, conserving judicial resources and preventing inconsistent decisions—would not be furthered by allowing a party to assert estoppel and argue that certain changes should be made to the prior court's holding.

Infringement

Having determined that Judge Darrah's construction of the disputed claims will be applied in this matter, the court must now determine whether Impax has infringed the patentee's rights. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1581-82 (Fed. Cir. 1996). An infringement analysis requires a comparison of the properly-construed claims to the accused device to determine whether that device has all of the limitations, either literally or under the doctrine of equivalents, as the claimed invention. Zebco, 175 F.3d at 988. Determination of infringement is a question of fact. Bai, 160 F.3d at 1353. In order to prove infringement, the burden is on the patentee to show that each and every limitation of the claims asserted to be infringed is found in the accused device. Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1565 (Fed. Cir. 1997).

According to the construction of the disputed claims, fenofibrate and a solid surfactant must be co-micronized in the absence of other excipients. Impax's ANDA describes a process whereby a *pre-micronized* fenofibrate is added to other excipients, and then a liquid surfactant is added to the

dry mixture causing wet granulation. (Impax Mem. at 13.) Impax does not have a manufacturing step where there is a mixture of particles consisting solely of fenofibrate and a solid surfactant. Because Impax's products do not contain a "co-micronized mixture of particles of fenofibrate and a solid surfactant," as recited in claim 1, or a manufacturing process that uses "co-micronization of the fenofibrate and a solid surfactant," as recited in claim 10, the court finds as a matter of law that there is no literal infringement of the '726 patent.

In addition to literal infringement, a party may infringe another's patent under the doctrine of equivalents. As explained above, the doctrine of equivalents allows a patentee to claim insubstantial alterations that were not captured in drafting the original patent claims, but which could be created through trivial changes. *Festo*, 122 S. Ct. at 1838. However, prosecution-history estoppel can prevent a patentee from relying on the doctrine of equivalents when the patentee relinquishes subject matter during the prosecution of the patent, either by amendment or argument. *Pharmacia*, 170 F.3d at 1376-77. In some cases, such as the one here, the Patent Trademark Office ("PTO") may reject one or more of the patentee's proposed claims. *Id.* In response, the patentee may narrow his claims — a decision which prevents him from later arguing that the subject matter covered by the original, broader claim was nothing more than an equivalent (*i.e.*, prosecution-history estoppel). *Id.* In a similar way, prosecution-history estoppel may also be based on *arguments* made by the patentee before the PTO.

Impax argues that this court is bound under collateral estoppel principles to follow the *Novopharm* court's decision that the doctrine of prosecution-history estoppel precludes Fournier's claim of infringement under the doctrine of equivalents. As with the claim construction determination, all four considerations for applying collateral estoppel are met with respect to Judge

Darrah's determination that Fournier is estopped from arguing infringement under the doctrine of equivalents. Because the patent and its prosecution history are the same in this case as in *Novopharm*, a determination of prosecution-history estoppel here is identical to that decided by Judge Darrah in *Novopharm*. Prosecution-history estoppel was actually litigated in the *Novopharm* case. Judge Darrah could not have granted summary judgment to Novopharm without deciding the prosecution-history estoppel issue, so it was essential to the judgment. Finally, Fournier had a full and fair opportunity to litigate prosecution-history estoppel. In light of this, the court follows the *Novopharm* court in concluding that Fournier cannot establish that Impax's product literally infringes the '726 patent.

In addition, even if the court were not bound under collateral estoppel, the court is persuaded by Judge Darrah's reasoning and would similarly bar Fournier from relying on a doctrine of equivalents argument. In *Novopharm*, the court looked to the prosecution history and found that the patentee of the '726 patent distinguished its process and product from those achieved by adding a surfactant or by micronizing the fenofibrate on its own or by intimately mixing the separately micronized fenofibrate and surfactant. *Novopharm*, 2002 U.S. Dist. LEXIS 4659, at *24. Therefore, "based on the arguments made during the prosecution of the patent . . . and the arguments made during reexamination," the court concluded that "Plaintiff [Fournier] relinquished a product and process that involved either adding a surfactant by itself or by micronizing the fenofibrate on its own [as done by defendant] or by intimately mixing the separately micronized fenofibrate and surfactant."

Id. at *24-25. Like the defendant in the *Novopharm* case, Impax's process uses fenofibrate that has been micronized by itself. As did the *Novopharm* court, the court concludes that Fournier is estopped from arguing infringement under the doctrine of equivalents for claims 1 or 10.

Conclusion

Based on the findings above relating to claims 1 and 10, Impax's product does not infringe the '726 patent. Further, claims 2-7 and 11-12 depend from claim 1. In light of the court's findings as to claims 1 and 10, there likewise may be no finding of infringement for the dependent claims. Wahpeton Canvas Co., Inc. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed. Cir. 1989) ("It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to have been infringed."). For the foregoing reasons, defendant Impax's motion for partial summary judgment of non-infringement is granted.

ENTER:

inited States District Judge

DATED:

March 26, 2003